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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,508	TROYER ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response filed November 1, 2004 concerning the restriction requirement set forth in the previous Office action has been received and entered. Applicants state in their November 1, 2004 response that the only claims remaining in the instant Divisional application are claims 22-28 (the Group II invention) - i.e., claims 1-21 had already been canceled in an earlier preliminary amendment. Accordingly, the restriction requirement set forth in the previous Office action is hereby vacated.

Claims 22-28 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22, 25, 26, and 27are rendered vague and indefinite by the phrases "a source of" (claims 22 and 27) and "the sources of" (claim 25) because it is unclear by these ambiguous phrases as to what is actually being defined - e.g., a health food store is a source of omega-3 fatty acid, omega-6 fatty acid, and magnesium. In addition, fish (such as that which is consumed in a meal comprising fish or fish soup) is a source of these agents. In addition, this phrase does not adequately define if the preparation actually contains these agents - e.g., fish is a source of these fatty acids, however that does not necessary mean that fish components other than these fatty

acids are being defined, as instantly drafted. It is suggested that this ambiguous phrase be omitted from these claims and dependent claims.

Claim 28 is rendered vague and indefinite by the phrase "the preparation of claim 27 containing ... and GLA" for the following reason. The term "GLA" therein lacks antecedent basis with respect to an actual ingredient within the preparation of the preceding claims from which claim 28 depends - i.e., claim 28 depends from claim 27 which depends from claim 22. The preparation defined by claim 22 recites "micronutrient cofactors effective to support and enhance conversion of linoleic acid to gamma-linolenic acid" (GLA) and claim 27 defines the micronutrients to include vitamin B6 and a source of magnesium. Accordingly, it is unclear if the GLA defined in claim 28 is, in fact, an actual ingredient within the claimed preparation or if this term is meant to perhaps define some other micronutrient (such as vitamin B6 or magnesium) that converts linoleic acid to GLA.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Abbruzzese et al. (US 6,077,828), by DeMichele et al. (US 5,223,285), by Garleb et al. (US 5,308,832), by Pellico (US 5,817,695), or by Alexander et al. (US 5,231,085).

An oral preparation comprising a source of omega-3 fatty acid, a source of omega-6 fatty acid, vitamin A, micronutrients such as vitamin B6 and magnesium, and an antioxidant such as vitamin C is claimed.

Abbruzzese et al. teach oral pharmaceutical compositions (preparations) comprising omega-3 and omega-6 fatty acids (please note that Abbruzzse et al. teach that dietary oils such as black currant oil are a good source of such fatty acid blends - see, e.g., col 7, lines 51-57), vitamin A, vitamin B6, magnesium, and vitamin C (also known as ascorbic acid). In addition, the oral pharmaceutical compositions (preparations) disclosed by Abbruzzese et al. are above the minimum amounts instantly claimed/disclosed - thus, in effective amounts (see, e.g., col 10, line 4 -col 11, line 62).

DeMichele et al. teach oral pharmaceutical compositions (preparations) comprising omega-3 and omega-6 fatty acids (from a blend of oils including fish oil, borage seed oil -which DeMichele et al. also disclose is also a good source of GLA, canola oil, etc), vitamin A, vitamin B6, magnesium, and vitamin C. In addition, the oral pharmaceutical compositions (preparations) disclosed by DeMichele et al. are above the minimum amounts instantly claimed/disclosed - thus, in effective amounts (see, e.g., col 6, lines 43-46; col 13, line 45 - col 14, line 10; col 16, Table 7, col 18, Table 8).

Garleb et al. teach oral pharmaceutical compositions (preparations) comprising omega-3 and omega-6 fatty acids (from a blend of oils including marine/sardine oil, borage seed oil - which Garleb et al. also disclose is also a good source of GLA, canola oil, etc), vitamin A, vitamin B6, magnesium, and vitamin C. In addition, the oral pharmaceutical compositions (preparations) disclosed by Garleb et al. are above the minimum amounts instantly claimed/disclosed - thus, in effective amounts (see, e.g., col 4, lines 31-32, col 13, Table 13).

Pellico teaches oral pharmaceutical compositions (preparations) comprising omega-3 fatty acids within cod liver oil (see, e.g., instant specification, page 8, lines 18-21, which states that a major source of omega-3 fatty acids is cold water fish such as cod), omega-6 fatty acids within corn oil (please note, as evidenced by Alexander et al., corn oil inherently comprises omega-6 fatty acids - see, e.g., Alexander et al: col 3, lines 41-48), vitamin A, vitamin B6 (also known as pyridoxine), magnesium sulfate, and vitamin C (also known as ascorbic acid). In addition, the oral pharmaceutical compositions (preparations) disclosed by Pellico are above the minimum amounts instantly claimed/disclosed - thus, in effective amounts (see, e.g., cols 8-9, Example 1).

Alexander et al. teach oral pharmaceutical compositions (preparations) comprising omega-3 fatty acids (including from menhaden fish oil), omega-6 fatty acids (including from corn oil - again please note Alexander et al. discloses that corn oil comprises omega-6 fatty acids - see, e.g., col 3, lines 41-48), vitamin A, vitamin B6, magnesium, and vitamin C. In addition, the oral pharmaceutical compositions (preparations) disclosed by Alexander et al. are above the minimum amounts instantly claimed/disclosed - thus, in effective amounts (see, e.g., col 3, lines 41-48; col 6, Example 1).

Please note that "the patentability of a product does not depend upon its method of production". Accordingly, if not expressly taught by one or more of the above references, the source from which the omega-3 and/or omega-6 fatty acids are obtained (e.g., instant claim 25) has not been afforded any patentable weight.

Therefore, each of the cited references is deemed to anticipate the instant claims above, as drafted.

Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeMichele et al. (US 5,223,285), or Garleb et al. (US 5,308,832), or Alexander et al. (US 5,231,085), in view of Bloch (US 4,788,180) .

Each of the primary references is relied upon for the reasons set forth above. None of the primary references expressly teach the use of magnesium sulfate within such pharmaceutical compositions.

Bloch beneficially teaches pharmaceutical compositions containing magnesium as an active ingredient therein, whereby the magnesium can be, and is preferably, in one of various ionic forms such as magnesium sulfate (see, e.g., col 4, lines 45-49).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize magnesium sulfate as the source of magnesium within the pharmaceutical compositions taught by each of the primary references based upon the beneficial teachings provided by Bloch, as discussed above. The adjustment of this type of conventional working condition (e.g., incorporating a particular, commonly employed magnesium ion therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over each of the primary references (in view of Bloch), especially in the absence of evidence to the contrary.

Claims 22 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pellico (US 5,817,695) and Abbruzzese et al. (US 6,077,828), with evidence provided by Alexander et al. (US 5,231,085).

Pellico teaches oral pharmaceutical compositions (preparations) for treating/reducing cancer (see entire document) which beneficially comprise omega-3 fatty acids within cod liver oil (see, e.g., instant specification, page 8, lines 18-21, which states that a major source of omega-3 fatty acids is cold water fish such as cod), omega-6 fatty acids within corn oil (please note, as evidenced by Alexander et al., corn oil inherently comprises omega-6 fatty acids - see, e.g., Alexander et al: col 3, lines 41-48), vitamin A, vitamin B6 (also known as pyridoxine), magnesium sulfate, and vitamin C (also known as ascorbic acid). In addition, the oral pharmaceutical compositions (preparations) disclosed by Pellico are above the minimum amounts instantly claimed/disclosed - thus, in effective amounts (see, e.g., cols 8-9, Example 1).

Abbruzzese et al. teach oral pharmaceutical compositions (preparations) for treating/reducing cancer (see entire document) which beneficially comprise omega-3 and omega-6 fatty acids (please note that Abbruzzse et al. advantageously teach that dietary oils such as black currant oil are a good source of such fatty acid blends - see, e.g., col 7, lines 51-57), vitamin A, vitamin B6, magnesium, and vitamin C (also known as ascorbic acid). In addition, the oral pharmaceutical compositions (preparations) disclosed by Abbruzzese et al. are above the minimum amounts instantly claimed/disclosed - thus, in effective amounts (see, e.g., col 10, line 4 -col 11, line 62).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instantly claimed ingredients for their known benefit (e.g., treating/reducing cancer) - based upon the beneficial teachings provided by the cited references (as discussed above), since each of the claimed ingredients is well known in the art for the same purpose (e.g., within anticancer compositions/preparations). The idea for combining them flows logically from their having been used individually in the prior art. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980); In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). The adjustment of particular conventional working conditions (e.g., incorporating black currant oil as a dietary oil source - as beneficially disclosed by Abbruzzese et al - within such anticancer compositions) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

With respect to the above art rejections (under USC 102 and under USC 103), it is noted that the cited references do not teach that their compositions can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference (especially since the amounts of the reference ingredients all exceed the instantly taught minimum amounts of the claimed/disclosed ingredients required to be effective amounts), thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and under U.S.C. 103 (see, e.g., MPEP 2112).

Claims 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin (US 5,120,760), Horrobin (US 5,328,691), Horrobin (Prog. Lipid Research, 1981 - parent IDS reference AR: titled Treatment of the Sicca Syndrome...), Varma (US 5,032,392), Valletta (US 6,248,368), and Van Niewuw Amerongen et al. (US 5,886,054).

A preparation for treating insufficient glandular production of lubricating liquids (such as dry eyes) comprising effective amounts of a source of omega-3 and omega-6 fatty acids, vitamin A, micronutrient cofactors, and a water-soluble antioxidant is claimed. Dependent claims include the micronutrient cofactors comprising vitamin B6 and/or magnesium, the antioxidant comprising ascorbic acid (vitamin C), the fatty acid sources comprising black currant oil, the preparation further comprising fish oil as a source of omega-3 fatty acid, and the preparation further comprising mucin.

The Horrobin references beneficially teach oral compositions useful for treating Sjogren's syndrome, an autoimmune disease which displays symptoms of dry eyes and dry mouth. The disclosed active agents within the compositions of the Horrobin references include oils containing omega-3 and/or omega-6 fatty acids - such as black currant oil and cold fish oil, vitamin C, and/or vitamin B6 (pyroxidine) - see, e.g., '760 - col 3, line 30 - col 6, line 7; '691 - col 2, line 28 - col 7, line 21; Prog. Lipid Research reference - entire document.

Varma discloses that it is well known in the art to orally administer Vitamin A palmitate (which is the same type of Vitamin A instantly disclosed) to treat dry eyes (see, e.g., col 1, lines 53-55).

Valletta beneficially teaches that orally administered magnesium compounds, such as various magnesium salts (preferably in association with Vitamin B6) are therapeutically useful in treating Sjogren's syndrome (see, e.g., abstract, col 3, line 56 - col 5, line 5).

Van Niewuw Amerongen et al. discloses that it is well known in the art to use animal mucins as a saliva substitute (thus orally administered) to relieve the complaints of dry mouth and dry eyes (see, e.g., col 1, lines 31-34).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980); *In re Sussman,* 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1654